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**IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH
CENTRAL DIVISION**

**NATISHAA PIERCE, Individually and
as Personal Representative of the Estate of
RONALD PIERCE,**

Plaintiff,

v.

**MYLAN LABORATORIES, INC; MYLAN
TECHNOLOGIES, INC., and MYLAN
TECNOLOGIES,**

Defendants.

**PLAINTIFF'S ORIGINAL COMPLAINT,
AND JURY DEMAND**

Case No.: _____

Plaintiff Natisha Pierce, individually and as the personal representative of the Estate of Ronald Pierce, ("Plaintiff"), files this Original Complaint and Jury Demand against Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc. (collectively, the "Mylan Defendants") and for cause of action would show:

PARTIES

1. Plaintiff Natisha Pierce is an individual residing in Utah. Plaintiff is the wife and surviving spouse of Ronald Pierce ("Decedent") and the duly appointed personal representative of Decedent's estate. Plaintiff brings this action on her own behalf, as a wrongful death beneficiary, on behalf of Decedent's estate, and on behalf of Decedent's other wrongful death beneficiaries, including, but not limited to: (1) Judy Pierce (Decedent's mother); (2) Ronald Pierce, Sr. (Decedent's Father); (3) Brandon Pierce (Decedent's son); (4) Justin Pierce (Decedent's son); (5) Matthew Pierce (Decedent's son); (6) Sammie Jo Pierce (Decedent's daughter); (7) Kirk Pierce (Decedent's son); (8) Taylor Leota (Decedent's Step-Daughter); and (9) Gabriel Leota (Decedent's Step-Son.).
2. Defendant Mylan, Inc. (formerly known as Mylan Laboratories, Inc.) is a corporation organized and existing under the laws of the State of Pennsylvania. Mylan, Inc. has done and is doing business in Utah, but it does not maintain an agent for service of process in this state. Mylan, Inc. may be served by delivering a summons and copy of the complaint to Corporation Service Company, 209 West Washington Street, Charleston. West Virginia 25302.
3. Defendant Mylan Pharmaceuticals, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the West Virginia. Mylan Pharmaceuticals, Inc. has done and is doing business in Utah, but it does not maintain an agent for service of

process in this state. Mylan Pharmaceuticals may be served by delivering a summons and copy of the complaint to Corporation Service Company, 209 West Washington Street, Charleston. West Virginia 25302.

4. Defendant Mylan Technologies, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the State of West Virginia. Mylan Technologies, Inc. has done and is doing business in Utah, but it does not maintain an agent for service of process in this state. Mylan Technologies, Inc. may be served by delivering a summons and copy of the complaint to Corporation Service Company, 209 West Washington Street, Charleston. West Virginia 25302.

JURISDICTION AND VENUE

5. Pursuant to 28 U.S.C. § 1332, this Court has jurisdiction over this case because it is a lawsuit between parties of diverse citizenship and the amount in controversy exceeds \$75,000. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim (i.e., Decedent's fentanyl overdose and resulting death) occurred in this district.

FACTS

6. This suit arises out of the wrongful death of Decedent due to the wrongful conduct of Defendants. Decedent was given a prescription for 75 mcg fentanyl patches. The prescription was filled with 75 mcg Mylan (fentanyl transdermal system) patches (the

“Patch”) from a local pharmacy. Decedent was wearing one of these patches (the “Pierce Patch”) at the time of his death and it was the cause of his death. The Pierce Patch worn by Decedent at the time of his death was designed, manufactured, marketed, and distributed by the Mylan Defendants.

7. The Patch is a matrix patch containing the drug fentanyl. Fentanyl is an extremely dangerous drug that is at least 80 times stronger than morphine. Fentanyl is classified as a Schedule II controlled substance by the FDA and is generally used to relieve pain.
8. The Patch is applied by the patient and delivers fentanyl through the patient’s skin.
9. The Mylan Defendants design, manufacture, market and sell the Patch with the intention that it will release a certain amount of fentanyl into a patient at a certain rate, and thus produce a certain level of fentanyl in the blood of the patient. In other words, if a Patch functions as intended and it is properly used by the patient, the patient should not receive a harmful dose of fentanyl. Decedent never abused the Patch or used it inappropriately.
10. Decedent was prescribed Mylan 75mcg patches for pain. Decedent was found dead on July 2, 2008. A toxicology report indicated Decedent had a fentanyl level of 8.6ng/mL, which is in the lethal range and was a cause of Decedent’s death.

CAUSES OF ACTION

A. FIRST CAUSE OF ACTION: STRICT PRODUCT LIABILITY.

11. The Mylan Defendants are liable under the theory of product liability as set forth in §§402A and 402B of the Restatement of Torts 2d. The Mylan Defendants at all times

material hereto engaged in the business of designing, manufacturing, selling, marketing, and/or supplying the Patch, including the Pierce Patch. The Pierce Patch was in defective condition at the time it was designed, manufactured, sold, and/or marketed by the Mylan Defendants and at the time it left their possession because it was unreasonably dangerous. The Pierce Patch was unreasonably dangerous and, therefore, defective because, *inter alia*, it gave Decedent a much higher dose of fentanyl than a properly functioning patch should have given him. As discussed below, Defendants failed to warn of the Pierce Patch's defective condition or utilize a safer alternative design. Decedent was unaware of the defective condition of the Pierce Patch at the time he used the product in the manner and for the purpose it was intended. The defective condition was a legal cause of Decedent's death and the damages described herein. The Pierce Patch was in the control of the Mylan Defendants at the time the defect occurred. Further, the injury sustained by Decedent, fentanyl intoxication, was the exact type of injury that a defective Patch causes. The Pierce Patch reached Decedent without any substantial change in its condition. The Pierce Patch presented an unreasonable risk of injury in that the risk was one which a reasonably prudent person having full knowledge of the risk would find unacceptable. Because of the nature of ingredients or natural characteristics of the Pierce Patch, use of it involved a substantial risk of injury. The exposure to risk of injury was unreasonable taking into consideration a balancing of the dangers and benefits resulting from the product's use.

1. Manufacturing Defect

12. More specifically, the Pierce Patch was defective because of the existence of a manufacturing flaw which rendered the product unreasonably dangerous at the time it left the Mylan Defendants' control. The Pierce Patch was unreasonably dangerous because it did not conform to its intended design and failed to perform as safely as the intended design would have performed. The Pierce Patch was unreasonably dangerous beyond that which would be contemplated by the ordinary user. The manufacturing defect was a legal cause of Decedent's death and the damages claimed herein.

2. Marketing Defect

13. Pleading further and without waiver of the foregoing, the Patch was defective because the Mylan Defendants failed to warn of risks that were known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time the Pierce Patch was manufactured and distributed. The Mylan Defendants knew or had reason to know the Patch was or was likely to be unreasonably dangerous in the use for which it was made. The danger was not open and obvious. The Mylan Defendants failed to exercise reasonable care to warn Decedent or her doctor of the dangerous condition or the facts that made it dangerous. The Mylan Defendants' failure to warn was a legal cause of Decedent's death and the damages claimed herein.
14. For these reasons, the Defendants are strictly liable under applicable products liability law without regard to proof of negligence and gross negligence. However, if it be

necessary, Plaintiff would show that the Pierce Patch was designed, manufactured, sold, supplied, and/or marketed in a defective condition and such defects were a legal cause of Decedent's death and the damages claimed herein.

B. SECOND CAUSE OF ACTION: NEGLIGENCE.

15. The Mylan Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, sale, or distribution of the Patch into the stream of commerce, including, without limitation, a duty to provide adequate warnings and instructions, including, without limitation, a duty to assure that the Patch did not cause users to suffer from unreasonable, dangerous side effects, including death. The Mylan Defendants failed to exercise ordinary care in the design, manufacture, marketing, sale, testing, quality assurance, quality control or distribution of the Pierce Patch into interstate commerce in that the Mylan Defendants knew or should have known that the Patch created a high risk of unreasonable, dangerous side effects, including death.
16. More specifically, the Mylan Defendants' negligence in the design, manufacture, marketing, testing and sale of the Patch, includes, without limitation:
 - a. Inadequate and/or insufficient warnings regarding the product;
 - b. Failure to use due care in designing and manufacturing the Patch;
 - c. Failure to use proper materials reasonably suited to the manufacture of the Patch;
 - d. Failure to use due care to test and inspect the Patch to determine its durability and functionality for the purpose for which it was intended;

- e. Failure to conduct adequate testing and post-marketing surveillance to determine the safety of the Patch;
 - f. Inadequate or insufficient inspection for defects;
 - g. Inadequate and/or insufficient research into the safety of the product prior to sale;
 - h. Inadequate and/or insufficient monitoring or research regarding adverse events;
 - i. Failure to provide adequate training, knowledge or information to physicians, distributors, or sellers of the product;
 - j. Failure to adequately warn individuals of the dangerous and lethal side effects of the product;
 - k. Formulating and designing the product;
 - l. Making the product;
 - m. Inspecting and testing the product;
 - n. Packaging the product; and
 - o. Other and further particulars as will be proven at trial.
17. The negligent conduct of the Mylan Defendants, as alleged above, was a legal cause of Decedent's death and the damages claimed herein.

C. THIRD CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION.

18. The Mylan Defendants knew or should have known that the Patch created a high risk of unreasonable, dangerous side effects, including that proper use of the Patch can cause death. Mylan failed to communicate to Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury and/or death.
19. Therefore, Plaintiff brings this cause of action against the Mylan Defendants under the

theory of negligent misrepresentation for the following reasons:

- a. The Mylan Defendants failed to warn of the defective condition of the Patch, as manufactured and/or supplied by the Mylan Defendants;
- b. The Mylan Defendants, individually, and through their agents, representatives, distributors and/or employees, negligently misrepresented material facts about the Patch in the course of their business in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, the Mylan Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;
- c. The above misrepresentations were made to Decedent, physicians, pharmacists, as well as the general public;
- d. The Mylan Defendants intended to induce others to rely on their representations, including, without limitation, Decedent, physicians, and pharmacists;
- e. Decedent and others, including, without limitation, Decedent's physician(s) and her pharmacist(s), justifiably relied on Defendants' misrepresentations; and
- g. Consequently, Decedent's use of the Patch was to her detriment. The Mylan Defendants' negligent misrepresentations were a legal cause of the death of Decedent and the damages claimed herein.

D. FOURTH CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY.

- 20. The Mylan Defendants made affirmations of fact or promises regarding the safety and effectiveness of the Pierce Patch (including, without limitation, the safe, time-released delivery of fentanyl) which became part of the basis of the bargain. The Mylan

Defendants guaranteed that the Pierce Patch would conform to their affirmations. Without limitation, the Pierce Patch was failed to conform to the Mylan Defendants' express warranties because it malfunctioned during normal use. The Mylan Defendants' breach of their affirmations of fact or promise regarding the Pierce Patch was a legal cause of Decedent's death and the damages claimed herein.

E. FIFTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY OF FITNESS.

21. The Mylan Defendants had reason to know that the particular purpose for which the Pierce Patch was to be used. The Mylan Defendants had reason to know that the buyer was relying on the skill and judgment of the Mylan Defendants to select or furnish suitable products. The Pierce Patch supplied by the Mylan Defendants was unfit for the particular purposes for which it was purchased. This lack of fitness for the product's purpose was a legal cause of the death of Decedent and the damages claimed herein. As such, Plaintiff is entitled to recover under Utah Code Ann. § 70A-2-315.

F. FIFTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY.

22. The Pierce Patch supplied by the Mylan Defendants was unmerchantable in that it was unfit for its ordinary purpose, was not of even quality and was not adequately labeled. This lack of merchantability was a legal cause of the death of Decedent and the damages claimed herein. Plaintiff is entitled to recover under Utah Code Ann. § 70A-2-314.

F. GROSS NEGLIGENCE AND INTENTIONAL MISCONDUCT.

23. In addition to the foregoing, the Mylan Defendants' conduct was of such a character and degree as to constitute willful, malicious, intentional misconduct and gross negligence. The Mylan Defendants had actual knowledge of the wrongfulness of the conduct and the

high degree of probability that substantial injury or damage would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage. Moreover, the conduct of the Mylan Defendants was so reckless or wanting in care that it constituted a knowing and reckless indifference to the life, safety, or rights of persons exposed to such conduct.

DAMAGES

24. The unlawful acts and practices described above were a legal cause of Decedent's death and the damages claimed in this lawsuit. Therefore, Plaintiff, on behalf of Decedent's Estate seeks all damages available under Utah law including, without limitation: (a) loss of financial support of Decedent; (b) medical and funeral expenses paid on behalf of Decedent; (c) future loss of Decedent's society, support and services; (d) loss of Decedent's affection, comfort, counsel and advice; (e) lost companionship, care and solicitude; and (f) mental pain and suffering from the date of injury.
25. The Mylan Defendants had actual knowledge of the wrongfulness of the conduct and the high degree of probability that substantial injury or damage would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage. Moreover, the conduct of the Mylan Defendants was so reckless or wanting in care that it constituted a knowing and reckless indifference to the life, safety, or rights of persons exposed to such conduct. Furthermore, the Mylan Defendants knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug Administration under its regulations, which information was material and relevant to Plaintiff's harm. *See* Utah Code Ann. §78-18-2. Therefore, Plaintiff seeks recovery of punitive, exemplary and any other additional damages that the law allows under the

causes of action asserted above.

CONDITIONS PRECEDENT

26. All conditions precedent to Plaintiff's right to recover the relief sought herein have occurred or have been performed.

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants be cited to appear and answer, and that the Court set the case for jury trial, and that judgment be entered against the Mylan Defendants, jointly and severally, for the damages set forth herein above; for pre-judgment and post-judgment interest and costs of suit; and for such other and further relief to which Plaintiff may be justly entitled.

Respectfully Submitted,

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